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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/674,184 | 09/29/2003 | Edward Rhad | END-5033 | 1958 |
| 27777 7590 01/09/2007 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | EXAMINER APANUS, MICHAEL | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3736 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 01/09/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/674,184 | RHAD ET AL. | |
| | Examiner | Art Unit | |
| | Michael Apanius | 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,9-21 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) 9-17 and 24-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the amendment filed on 10/2/2006. The amendments to claims 1-3, 5 and 18-21 and the cancellation of claims 6-8, 22 and 23 are acknowledged. Currently, claims 1-5, 9-21 and 24-31 are pending, while claims 9-17 and 24-31 remain withdrawn from consideration.

Claim Objections

2. Claim 19 is objected to because of the following informalities: at claim 19, lines 2-3, it appears that "the electrical contacts" should be --electrical contacts--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 3, 5, 19 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 3, 5, 19 and 21 appear to contradict the independent claims. Amended independent claim 1 now recites, "a controller ...

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generates a threshold response” and amended independent claim 18 now recites, “the controller generates a threshold response”. However, claims 3, 5, 19 and 21 recite, “wherein the finger touch response apparatus generates the threshold response”.

Therefore, claims 3, 5, 19 and 21 are rendered indefinite because it is unclear whether the controller or the finger touch response apparatus generates the threshold response.

6. Furthermore, claims 1-5 and 18-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Although the original disclosure provides support for the finger touch response apparatus generating a threshold response, the original disclosure does not appear to provide support for the controller generating a threshold response.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hickie (US 2002/0017296). Hickie discloses a conscious sedation system comprising:
a) a controller (14) which generates a request for a predetermined response from a

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patient, wherein the controller analyzes at least a response generated by the patient, b) a response testing apparatus (256 in figure 11 and paragraph 111) including: a request assembly (264) which communicates to the patient the request generated by the controller; and a response assembly (266) which is used by the patient to generate the response and which communicates the response to the controller, wherein the request assembly and/or the response assembly is attachable to the patient's fingers (see figure 13A and paragraphs 118-120) and wherein the response is generated by movement of the patient's fingers. The controller generates a threshold response (paragraph 112, lines 9-15) and the threshold response varies based on the response generated by the patient.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 2-5 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickie (US 2002/0017296) in view of Ellis (US 4,674,330). However, Hickie does not expressly disclose a finger touch response apparatus comprising electrical contacts located on receptacles, a finger touch response apparatus that generates a threshold response when electrical contacts are moved within a predetermined proximity of each other, or a strain gage. Ellis teaches a finger touch response apparatus (figure 13) for

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the purpose of obtaining accurate measurements regardless of the patient's precise hold on the apparatus (column 2, lines 7-14). One having ordinary skill in the art would recognize the importance of the patient's precise holding position because as a patient is undergoing sedation the placement of their grip might change on the apparatus due to diminished bodily control. Furthermore, it is well known in the art that the grip and pinch strength apparatus as taught by Ellis is an art-recognized equivalent input device to the button apparatus of Hickie. The finger touch response apparatus of Ellis comprises receptacles (2', 3') attachable onto the patient's fingers, strain gages (14', 15', 16', 17'), electrical contacts (6', 7') on the receptacles, and a biasing member (13'). Although Ellis may not expressly disclose that the exposed metal tips (6', 7') are electrical contacts, the exposed metal tips are deemed to be electrical contacts because they are capable of conducting electricity and forming electrical connections. The apparatus generates a threshold response when the electrical contacts are moved within a predetermined distance of each other and when a predetermined force is registered by the strain gage. The response is continuous and can be carried based on the patient's grip force (column 4, line 65 - column 5, line 4). It would have been obvious to one having ordinary skill in the art at the time of invention to have used the finger touch response apparatus as taught by Ellis in the conscious sedation system of Hickie in order to make accurate measurements regardless of the patient's precise holding position on the apparatus and because it is an art-recognized equivalent input device.

Response to Arguments

11. Applicant's arguments filed 10/2/2006 have been fully considered but they are not persuasive.

12. Applicant argues that Hickle does not teach or suggest a threshold response or the fact that the controller can vary the threshold response based on the response generated by the patient. In response, it is respectfully noted that the controller generates a threshold response (paragraph 112, lines 9-15) and that the threshold response varies based on the response generated by the patient. For example, the threshold response varies based on whether or not the patient even responds and/or based on the latency of the response.

13. Applicant argues that the combined art of record fails to teach or suggest the limitations of the amended independent claims. Applicant further argues that there is no teaching, suggestion, or motivation to modify or combine the references to obtain the invention presently claimed. In response, the claim limitations are met as noted above and there is motivation to combine Ellis with Hickle as noted above in the rejection.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

15. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8am-4:30pm.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA



MAX HINDENBURG

SENIOR PATENT EXAMINER

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